FDA 510(k) Premarket Notification

K110992 ENSPIRE DEBRIDER SYSTEM

CLEARED

Oct 21, 2011
196 days to decision

K110992 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k110992/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Apr 8, 2011
Decision date	Oct 21, 2011
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spine View, Inc.**
Location	Fremont, CA, US
Contact	MBITHI MUTHINI
510(k) history	9 submissions · 9 cleared · 2008-2016